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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO EXCLUDE CERTAIN OPINIONS OF DARREN R. HURST, M.D., AND SUPPORTING MEMORANDUM OF LAW

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

The fact that Dr. Hurst is an interventional radiologist does not qualify him to offer the meta-analysis-like opinions contained in his Rule 26 Report. It does not qualify him to offer opinions about IVC filters grounded in regulatory issues, engineering, epidemiology, or metallurgy. And being an interventional radiologist does not give Dr.

Hurst a pass on identifying a methodology to assure that his opinions are based on sufficient facts or data, that they are the product of reliable principles and methods, and that he reliably applied the principles and methods to the facts of this case. The Plaintiffs' Response[1] does nothing to address these issues. Moreover, Dr. Hurst's opinions about caudal migration, issues surrounding the Meridian Filter, and "reasonable expectations of physicians" are his personal, speculative, and *ipse dixit* opinions that should be excluded.

A. Dr. Hurst's Opinion that Bard's Filters Have "Much Higher Complication Rates" Compared to Other IVC Filters Is Inadmissible Because Dr. Hurst Is Not Qualified To Offer It and Has Identified No Reliable Methodology To Arrive at His Opinion.

As an interventional radiologist, Dr. Hurst is undoubtedly qualified to offer opinions about the medical literature and his experience with IVC filters. But in offering opinions that Bard's filters have "much higher complication rates" than other filters, he crosses a line from analyzing individual articles in the medical literature into conducting a meta-analysis of thousands of articles in the literature concerning various complication modes for many different IVC filters. In their Response Brief, the Plaintiffs have not identified anything in Dr. Hurst's background that would provide the Court assurance that Dr. Hurst has sufficient "knowledge, skill, experience, training, or education" to offer such an opinion. The Plaintiffs cite *Ericson v. City of Phoenix*, No. CV-14-01942-PHX-JAT, 2016 WL 6522805 (D. Ariz. Nov. 3, 2016), because the court allowed a nurse practitioner, who had "extensive" knowledge and experience about strangulation, to testify about the effects of an officer's carotid hold on the decedent's death. But here, nothing in the record suggests that Dr. Hurst has extensive (or any) knowledge and experience in conducting meta-analyses. Rather, as discussed in Bard's Motion, Dr. Hurst is straying into an area outside the scope of his qualifications.

[1] Plaintiffs filed a separate Omnibus Statement Of Law And Generally-Applicable Arguments In Opposition To Bard's Motions To Exclude Plaintiffs' Experts Under Rule 702 And Daubert (Doc. 7799). Plaintiffs' Omnibus Statement is not directed at any specific Daubert motion Bard filed. As such, Bard does not respond to the Omnibus Statement but instead will address any necessary issues in the context of its individual Daubert replies.

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Even if Dr. Hurst has sufficient qualifications to offer such an opinion, he has not identified any methodology by which he arrived at his opinion. He cites an article by Deso and claims that "the Deso study is a meta-analysis," (Hurst Dep. Tr., 57:11-12, July 21, 2017, excerpt attached as Exhibit A), but Deso is not a meta-analysis. A meta-analysis is a quantitative, formal, epidemiological study design used to systematically assess previous research studies to derive conclusions about that body of research, often by pooled analysis and examination of variability or heterogeneity in study results. *See, e.g.*, Haidich, Meta-analysis in Medical Research, 14 Hippokratia 29 (2010). The authors of Deso, on the other hand, purported to conduct a literature review, and assembled rates for certain adverse events on a table, listing only the highest rate for each event that they found referenced in any particular article. (Deso, *Evidence-Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type*, 33 Seminars in Interventional Radiology 93, 97 (2016), attached as Exhibit B.) Thus, Dr. Hurst's reliance on Deso does not support his opinion that Bard's filters have "much higher complication rates" than other filters because Deso is not a meta-analysis.[2]

In arriving at his opinions, Dr. Hurst identifies 67 articles on his list of "Literature Reviewed," 19 of which are editorials, guidelines, or literature reviews, such as the Deso article; and the substantial majority of the remaining 48 articles involve Bard filters (by comparison, Deso, which was just a literature review, searched over 1400 articles concerning 24 different filters). The number of articles on Dr. Hurst's "Literature Reviewed" list is far too small, and limited almost exclusively to Bard filters, to allow for the meta-analysis-like opinion regarding all filters that he offers. And Dr. Hurst does not identify if and how he conducted an epidemiological study that systematically assessed this medical literature to derive his conclusion that Bard's filters have "much higher complication rates" than other filters.

[2] At best, the Deso article would support an opinion that the Bard filters have rates that have been reported up to the highest rate identified by Deso for any particular complication.

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The Plaintiffs also argue that "with regard to his opinions about complication rates, Dr. Hurst found further support in Bard's internal documents." (Pls. Resp. Br. (Doc. 7811), at 6.) The Plaintiffs' counsel, however, provided Dr. Hurst with only 24 Bard internal e-mails and documents from among the 1.5 million documents produced in the litigation (0.0016%). Dr. Hurst does not identify how these documents played into arriving at a meta-analysis-like opinion. Such a threadbare basis for his opinion provides no assurances that Dr. Hurst's opinion is based on sufficient facts or data, that it is the product of reliable principles and methods, or that he reliably applied the principles and methods to the facts of this case. *See Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167, 1176 (1999) (Daubert requires the trial court to assure itself that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

In short, Dr. Hurst offers a meta-analysis-like opinion without any evidence in his background that he is qualified to offer such an opinion. And even if he were qualified, reliance on a single article that is not a meta-analysis and 24 internal Bard documents is an insufficient basis from which to derive such an analysis. Dr. Hurst identifies no methodology that he used to reliably arrive at his opinion that Bard's filters have "much higher complication rates" than other filters. Accordingly, the opinion should be excluded.

B. Dr. Hurst's Opinion that Bard's Filters Have "The Unacceptable Risk of Caudal Migration" Is an Inadmissible *Ipse Dixit* Opinion.

In their Response, the Plaintiffs have not identified any reliable basis or methodology for Dr. Hurst's opinion that Bard's G2, G2X, and Eclipse filters have an "unacceptable risk of caudal migration" or a "significant increased safety risk of caudal migration . . . over competitor filters." (Ex. A to Mot, Hurst Rule 26 Report Regarding Pl. Mulkey, at 10.) Nor could they, as Dr. Hurst appears to use his own definition of caudal migration that is different than how the term is discussed in the medical literature. "When I talk about the Bard filters and caudal migration, what I mean is basically a settling that

occurs with the filters, a splaying out of the legs." (Hurst Dep. Tr., 231:16-19, Aug. 7, 2017, excerpts attached as Exhibit C.) The medical literature discusses caudal migration, and migration in general, as "a change in filter position compared to its deployed position (either cranial or caudal) of >2 cm as documented by plain-film imaging, CT, or venography." (ACR-SIR-SPR, *Practice Parameter for the Performance of Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism*, at 3 (2016), attached as Exhibit D; Ex. B, Deso Article, at 94 (discussing migration as "movement of an IVC filter greater than 2 cm along the IVC beyond the initial placement position.").) Bard is aware of no article in the medical literature discussing caudal migration in the terms that Dr. Hurst defines it. Nor is Bard aware of articles in the medical literature comparing rates of caudal migration across different filters. Thus, Dr. Hurst's opinions can find no support in the literature. As such, the opinions are classic *ipse dixit*, inadmissible opinions. *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert").

C. Dr. Hurst's Regulatory-Based, Engineering-Based, Metallurgical-Based, and Subjective Opinions Should Be Excluded Because He Does Not Have the Requisite Qualifications and Has Not Identified a Reliable Methodology To Arrive at the Opinions.

In their Response, the Plaintiffs argue that "[i]t is as a treating physician who has implanted and retrieved IVC filters, served as an intermediary between the IVC manufacturers and patients, and conducted risk benefit analyses that Dr. Hurst provides opinions" (Pls. Resp. Br. at 8) about "early safety signals," "in vitro testing," "minimum arbitrary threshold for migration resistance," "ignoring their in-house studies, [and] risk analysis," "marketing materials falsely represent[ing]" newer generations of filters that were "unproven in their safety and efficacy," and that "patients [] were unknowingly participating in a decade-long open experiment with Bard retrievable filters." (Ex. A. to Mot., Rule 26 Report at 11.) The Plaintiffs have not identified what in Dr. Hurst's

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background as a treating physician allows him to render opinions about these issues or how his opinions are methodologically sound enough to reliably allow him reach them.

For example, the term "signals" is a regulatory and epidemiological concept. Evaluation of "in vitro testing" and "migration resistance" are engineering issues. Concluding that marketing materials "falsely represented newer generation devices as greatly improved strength and stability" requires engineering and metallurgical knowledge to determine relative strength and stability across devices. In their Response Brief, the Plaintiffs have not identified anything in Dr. Hurst's background that would provide the Court assurance that Dr. Hurst has sufficient "knowledge, skill, experience, training, or education" to offer these opinions.

Even if Dr. Hurst had sufficient qualifications to offer such an opinion, he has not identified any methodology by which he arrived at his opinions. While many of his opinions implicate Bard's bench testing of its filters, Dr. Hurst testified that he has only seen some of the bench test data, he has not reviewed Bard's 510(k) submissions, and he has not seen any of the various submissions that Bard made to the FDA concerning test data. (Ex. A, Hurst Dep. Tr., 69:8-14; 70:11-19.) Dr. Hurst reviewed only 24 internal Bard e-mails and documents in arriving at the many opinions that he provides in his Rule 26 Report. The Plaintiffs have not addressed how such a limited number of documents constitutes a methodologically sound way to allow Dr. Hurst to reliably make his broad opinions that Bard "ignor[ed] their in-house studies, [and] risks analysis," that Bard's "marketing materials falsely represented newer generation devices," that Bard's filters were "unproven in their safety and efficacy," and that Bard was using patients as "unknowing[] participant[s] in a decade-long open experiment with Bard retrievable filters." Nor has Dr. Hurst identified any objective standards that he used to arrive at his opinions. These types of opinions, therefore, should be excluded. *See, e.g., Staub v. Breg, Inc.*, No. CV 10-02038-PHX-FJM, 2012 WL 1078335, at *3 (D. Ariz. Mar. 30, 2012) (finding that the expert's opinions must be grounded in "objective standards" and that any opinions "grounded on nothing more than her personal views will be excluded.").

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D. The Plaintiffs Improperly Attempt To Shift the Burden of Proof Regarding Admissibility of Dr. Hurst's Opinions Premised on the Meridian Filter.

The Plaintiffs have the burden of proving the admissibility of Dr. Hurst's opinions that Bard should never have launched the G2/G2X Filter or the Eclipse Filter because the Plaintiffs experienced complications of caudal migration and tilt that the Meridian filter attempted to correct. (Ex. A to Mot., Rule 26 Report, at 11.) Dr. Hurst, however, never implanted a Meridian Filter. (Ex. A, Hurst Dep. Tr., 102:18-21.) He does not know the rates of complication regarding the Meridian Filter. (*Id.* at 102:22-25.) He does not know how the rates of complication for the Meridian Filter compares to the G2/G2X Filter or Eclipse Filter. (*See id.* at 103:1-8.) The Deso article that Dr. Hurst relies on so heavily for his opinions about complication rates does not identify any rates of complications reported for the Meridian Filter. (Ex. B, Deso article, at 97.) Bard is aware of no studies published in the medical literature concerning the Meridian Filter, and is aware of only two case reports in the medical literature reporting that a patient's Meridian Filter fractured. And the Plaintiffs' challenge in their Response Brief that Bard should identify documents or deposition testimony about what it communicated to physicians has no bearing on whether Dr. Hurst's opinions about the Meridian Filter relative to Bard's earlier generation filters have any indicia of reliability.

In short, Dr. Hurst simply has no basis on which to opine that the Meridian Filter was any better or worse than Bard's previous generation filters. Therefore, Dr. Hurst's opinions about what Bard should have done with its previous generation filters, and what Bard should have communicated to physicians concerning these filters,[3] all of which is grounded in Dr. Hurst's description of the Meridian Filter, necessarily are speculative

[3] As discussed in Bard's Motion, Dr. Hurst's opinions about what Bard communicated with physicians nationally are likewise speculative. (Mot. at 11.) Dr. Hurst's knowledge about Bard's marketing is limited to his personal experience with Bard's sales representatives, and "I haven't seen him [Bard's sales representative] in years." (Ex. A, Hurst Dep. Tr., at 69:3-4.) Although the Plaintiffs argue that Dr. Hurst reviewed marketing documents to determine what Bard told physicians nationally, none of the documents identified on his "Bard Materials and Depositions Reviewed" are promotional pieces for physicians. (Ex. A to Mot., Rule 26 Report, at Appendix.)

opinions that should be excluded.

E. Dr. Hurst's Opinions about "Reasonable Expectations of Physicians" and "Informed Consent" Are Inadmissible.

Part and parcel of Dr. Hurst's opinions about what Bard should have discussed with physicians are his opinions about the "reasonable expectations of physicians" and "informed consent," which the Plaintiffs discuss at length in their Response. (Pls. Resp. Br., at 4-5, 10-11.) These opinions, however, are inadmissible because they are not grounded in any reliable sources of authority and they do not satisfy any of the *Daubert* factors (i.e., they have not been tested or peer reviewed, they have no known rate of error, they have not been published, and the physicians have not identified their view as generally accepted in the medical community).[4] The Plaintiffs have not identified any cases where opinions about "reasonable expectations" of a physician in an "informed consent" context were admitted in a product liability case. Indeed, informed consent is not an element of any claim or defense, as it is strictly a medical malpractice concept; the Plaintiffs have cited nothing to the contrary, and Dr. Hurst's opinions, therefore, do not "fit" the case. The only cases that the Plaintiffs cite in their Response concerning informed consent are medical malpractice cases. *Scharf v. Trabucco*, No. 3:14-cv-8183-HRH, 2017 WL 105993 (D. Ariz. Jan. 11, 2017) (medical malpractice case premised on a hospital's failure to meet the standard of care regarding informed consent); *Saccuci v. United States*, No. CV-07-1277-PHX-GMS, 2009 WL 1531842 (D. Ariz. June 2, 2009)

[4] *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 556-57 (S.D.N.Y. 2004) (rejecting the Plaintiffs' arguments that their physician expert was "articulating general principles that physicians require accurate information on labels to make informed decisions" because "the clear import" of the opinions is that physicians would not have prescribed the Rezulin if different information had been provided to the medical community, which is speculative and therefore inadmissible); *In re Diet Drugs Prod. Liab. Litig.*, No. MDL 1203, 2001 WL 454586, at *18 (E.D. Pa. Feb. 1, 2001) (excluding an expert's opinion about how physicians would think and act if the company had provided additional adverse event information); *In re Diet Drugs Prod. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *12 (E.D. Pa. June 20, 2000) ("The court can easily preclude, from a *Daubert* viewpoint, the rendering of opinions by either of these [physician] witnesses as to a label's compliance with federal regulatory requirements or as to what doctors in general think, because the witnesses are not qualified for that.").

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(medical malpractice informed consent case). Finally, the "informed consent" AMA Code of Medical Ethics provision and opinion that Dr. Hurst cite in his Rule 26 Report, (Ex. A to Mot., Rule 26 Rep., at 8), say nothing about the information required to satisfy informed consent, such that Dr. Hurst's thoughts about what is required to satisfy informed consent are his personal and *ipse dixit* opinions. Thus, Dr. Hurst's opinions about "reasonable expectations of physicians" and "informed consent" should be excluded as part of excluding his opinions about what Bard told and should have told physicians.

CONCLUSION

The Plaintiffs have not met their burden of proof that Dr. Hurst's broad opinions should be admitted. Accordingly, the Court should limit his opinions to his proper areas of expertise concerning his clinical experience with IVC filters, interpretation and analysis of the Plaintiffs' radiological medical records, and his interpretation of articles in the medical literature.

DATED this 18th day of October, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that October 18, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

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